AMENDED IN ASSEMBLY APRIL 23, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 1139

Introduced by Assembly Member Lowenthal

February 21, 2003

An act to add Section 111247 to the Health and Safety Code, relating to medical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 1139, as amended, Lowenthal. ~~Medical~~ *Drugs and medical* devices: ~~di(2-Ethylhexyl) phthalate~~ *Di(2-ethylhexyl)phthalate* (DEHP).

Existing law, the Sherman Food, Drug, and Cosmetic Law, contains various provisions regarding the packaging, labeling, and advertising of food, drugs, devices, and cosmetics. Violation of any of these provisions is a crime.

This bill would prohibit any person, commencing January 1, 2005, from selling or otherwise distributing any *drug or* medical device containing~~di-(2-Ethylhexyl) phthalate~~ *Di(2-ethylhexyl)phthalate* (DEHP)~~ in this state. The bill would specify that this prohibition would not apply to any medical device for which there is no alternative device approved by the federal Food and Drug Administration~~ *, which is used for a high-risk medical procedure or in a high-risk group, as determined by the federal Food and Drug Administration (FDA), unless that drug or medical device is clearly labeled with a specified statement. It would require the provision of a specified form by a seller of a drug or medical device containing DEHP to a purchaser if certain conditions exist, and would require any person, commencing on January 1, 2006, who sells*

or otherwise distributes any drug or medical device containing DEHP, which is not used for a high-risk procedure or in a high-risk group, to provide this specified form and follow certain prescribed procedures. Because a violation of the Sherman Food, Drug, and Cosmetic Law is a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 111247 is added to the Health and Safety Code, to read:

111247. (a) Commencing January 1, 2005, no person may sell or otherwise distribute any *drug or* medical device containing ~~di-(2-Ethylhexyl) phthalate (DEHP) in this state.~~

~~(b) Notwithstanding subdivision (a), this section shall not apply to any medical device for which there is no alternative device approved by the federal Food and Drug Administration.~~

111247. (a) Commencing January 1, 2005, no person may sell or otherwise distribute any drug or medical device containing Di(2-ethylhexyl)phthalate (DEHP), which is used for a high-risk medical procedure or in a high-risk group, as determined by the federal Food and Drug Administration (FDA), unless that drug or medical device is clearly labeled with the following statement:

"ATTENTION: THIS PRODUCT CONTAINS PHTHALATES."

(b) (1) Notwithstanding subdivision (a), if FDA approval is required prior to making a change to the product label as required by subdivision (a), the person that sells or otherwise distributes a drug or medical device covered under subdivision (a) shall distribute the form specified in paragraph (2) until the drug or medical device is labeled in accordance with subdivision (a). If the sale of the drug or medical device is made to an individual

hospital, the form shall be signed by the seller or distributor of the drug or medical device and by the medical director of the neonatal intensive care unit (NICU) and the medical director of the pediatric unit of the hospital that uses the drug. If the sale of the drug or medical device is made pursuant to a group purchasing plan, the form shall be signed by the seller or distributor of the drug or medical device, the person authorized to purchase the drug or medical device on behalf of each individual hospital, and by each medical director of a neonatal intensive care unit (NICU) and each medical director of a pediatric unit of a hospital that uses the drug or medical device. All forms shall be retained by the purchaser or medical director.

(2) The form specified in paragraph (1) and subdivision (c) shall include the following statement:

"This product contains Di(2-ethylhexyl)phthalate (DEHP) which is known to cause reproductive harm in male neonates, pregnant women carrying male fetuses, and peripubertal males. The federal Food and Drug Administration (FDA) has identified the following procedures as posing the highest risk of exposure to DEHP: exchange transfusion in neonates, extracorporeal membrane oxygenation (ECMO) in neonates, total parenteral nutrition (TPN) in neonates (with lipids in polyvinylchloride (PVC) bag), multiple procedures in sick neonates (high cumulative exposure), hemodialysis in peripubertal males, hemodialysis in pregnant or lactating women, enteral nutrition in neonates and adults, heart transplantation or coronary artery bypass graft surgery (aggregate dose), massive infusion of blood into trauma patient, and transfusion in adults undergoing ECMO. The FDA recommends considering DEHP-free medical products when these high-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peripubertal males.

Seller or Distributor	*Signature*	*Date*
Purchaser (Hospital)	*Signature*	*Date*

NICU Medical Director	*Signature*	*Date*
Pediatric Unit Medical Director	*Signature*	*Date”*

(c) Commencing January 1, 2006, any person who sells or otherwise distributes any drug or medical device containing Di(2-ethylhexyl)phthalate (DEHP), which is not used for a high-risk procedure or in a high-risk group, as specified in subdivision (a), shall provide the form and utilize the procedure specified in subdivision (b).

(d) For purposes of this section, a medical device does not include any diagnostic equipment, or other equipment that does not make any direct or indirect contact with a patient or is not connected to a patient in any way.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O